SAFE-GUARD® HORSE & CATTLE DEWORMER 92 G PASTE 10%

Intervet/Merck Animal Health

(fenbendazole)

(100 mg/g)

DESCRIPTION:

Safe-Guard® (fenbendazole) Paste 10% contains the active anthelmintic, fenbendazole. The chemical name of fenbendazole is methyl 5-(phenylthio)-2-benzimidazole carbamate.

The CAS Registry Number is 43210-67-9.

The chemical structure is:

Each gram of Safe-Guard® Paste 10% contains 100 mg of fenbendazole and is flavored with artificial apple-cinnamon liquid.

ACTIONS:

The antiparasitic action of Safe-Guard[®] Paste 10% is believed to be due to the inhibition of energy metabolism in the parasite.

INDICATIONS:

Horse: Safe-Guard[®] Paste 10% is indicated for the control of large strongyles (*Strongylus edentatus*, *S. equinus*, *S. vulgaris*), encysted early 3rd stage (hypobiotic), late 3rd stage and 4th stage cyathostome larvae, small strongyles, pinworms (*Oxyuris equi*), ascarids (*Parascaris equorum*), and arteritis caused by 4th stage larvae of *Strongylus vulgaris* in horses.

Safe-Guard[®] Paste 10% is approved for use concomitantly with an approved form of trichlorfon. Trichlorfon is approved for the treatment of stomach bots (*Gasterophilus* spp.) in horses. Refer to the manufacturer's label for directions for use and cautions for trichlorfon.

Beef and Dairy Cattle: Safe-Guard[®] Paste 10% is indicated for the removal and control of: Lungworm (*Dictyocaulus viviparus*); Stomach worms: (*Haemonchus contortus*, Ostertagia ostertagi, Trichostrongylus axei); Intestinal worms: (*Bunostomum phlebotomum*, Nematodirus helvetianus, Cooperia punctata & C. oncophora, Trichostrongylus colubriformis, Oesophagostomum radiatum).

Treats 8 animals of 500 lbs. each. Net Wt. 3.2 oz. (92g).

CONTRAINDICATIONS:

There are no known contraindications for the use of Safe-Guard® Paste 10% in horses or cattle. In dairy cattle, there is no milk withdrawal period.

PRECAUTIONS:

Horse: Side effects associated with Safe-Guard[®] Paste 10% could not be established in well-controlled safety studies in horses with single doses as high as 454 mg/lb. (1,000 mg/kg) and 15 consecutive daily doses of 22.7 mg/lb. (50 mg/kg). At higher dose levels, the lethal action of fenbendazole may cause the release of antigens by the dying parasites. This phenomenon may result in either a local or systemic hypersensitive reaction varying in severity from itching or a rash to increased respiration and collapse. A veterinarian should be consulted if this type of reaction is suspected.

Safe-Guard[®] Paste 10% has been evaluated for safety in pregnant mares during all stages of gestation with doses as high as 11.4 mg/lb. (25 mg/kg) and in stallions with doses as high as 11.4 mg/lb (25 mg/kg). No adverse effects on reproductivity were detected. The recommended dose for control of 4th

stage larvae of *Strongylus vulgaris*, 4.6 mg/lb. (10 mg/kg) daily for 5 consecutive days, has not been evaluated for safety in stallions or pregnant mares. Internal Parasites: Regular deworming at intervals of six to eight weeks may be required due to the possibility of reinfection.

Migrating Tissue Parasites: In the case of 4th stage larvae of *Strongylus vulgaris*, treatment and retreatment should be based on the life cycle and the epidemiology. Treatment should be initiated in the spring and repeated in the fall after a six-month interval.

Optimum Deworming Program for control of *S. vulgaris*: Optimum reduction of *S. vulgaris* infections is achieved by reducing the infectivity of the pastures. When horses are running on pasture, in temperate North America, maximum pasture infectivity occurs in October - December. If horses are removed from those pastures in January, pasture infectivity will decline to zero by July 1. Egg production of *S. vulgaris* is minimal from January through April, peaking in August and declining to minimal values in December.

Recommended Deworming Program: **December 1, February 1, April 1, June 1, August 1, October 1.

The two treatments which are in bold type are the recommended periods when the 5-day treatment regimen for the control of the migrating larvae of *S. vulgaris* should be performed.

**For other areas in the world, retreatment periods for the migrating larvae of S. vulgaris may be different; consult with your veterinarian.

CAUTION: When using Safe-Guard® (fenbendazole) Paste 10% concomitantly with trichlorfon, refer to the manufacturer's labels for use and cautions for trichlorfon.

WARNING:

Horse: Do not use in horses intended for human consumption.

DOSAGE:

Horse: Safe-Guard[®] Paste 10% is administered orally at a rate of 2.3 mg/lb. (5 mg/kg) for the control of large strongyles, small strongyles, and pinworms. Each mark on the plunger rod corresponds to a dose of 5 mg/kg (2.3 mg/lb.) for 250 lbs. body weight.

For foals and weanlings (less than 18 months of age) where ascarids are a common problem, the recommended dose is 4.6 mg/lb. (10 mg/kg) or two marks will deworm a 250 lb. horse.

For control of encysted early 3rd stage (hypobiotic), late 3rd stage and 4th stage cyathostome larvae and 4th stage larvae of *Strongylus vulgaris*, the recommended dose is 4.6 mg/lb. (10 mg/kg) daily for 5 consecutive days; administer two marks for each 250 lbs. body weight per day.

Horse: SEE PRECAUTIONS FOR RETREATMENT RECOMMENDATIONS.

WARNING:

Cattle: Cattle must not be slaughtered within 8 days following last treatment.

DOSAGE:

Beef and Dairy Cattle: Safe-Guard[®] Paste 10% is administered orally at a rate of 2.3 mg/lb (5 mg/kg) or 11.5 g Safe-Guard[®] (fenbendazole) Paste for 500 lb. body weight (227 kg). Under conditions of continuous exposure to parasites, retreatment may be needed after 4 - 6 weeks.

DIRECTIONS FOR USE:

- 1. Determine the weight of the animal.
- 2. Remove syringe tip.
- 3. Turn the dial ring until the edge of the ring nearest the tip lines up with zero.
- 4. Fully depress plunger and discard expelled paste. Syringe is ready for dosing.
- 5. Each mark on the plunger rod corresponds to a dose of 5 mg/kg (2.3 mg/lb.) for 250 lbs. body weight. Dial the ring edge nearest the tip back by one mark for each 250 lbs. body weight (do not underdose).

Examples:

250 lbs.	1 mark
500 lbs.	2 marks
750 lbs.	3 marks
1000 lbs.	4 marks
1500 lbs.	6 marks

- 6. Animal's mouth should be free of food. Insert nozzle of syringe through the interdental space and deposit the paste on the back of the tongue by depressing the plunger.
- 7. Repeat steps 1, 5 and 6 for each additional animal.

HOW SUPPLIED:

Safe-Guard® Paste 10% Horse and Cattle Dewormer is supplied in 92 gram syringes.

Store at or below 25°C (77°F).

Consult your veterinarian for assistance in the diagnosis, treatment and control of parasitism.

CAUTION: Keep this and all medication out of the reach of children.

Manufactured by DPT Laboratories, San Antonio, TX 78215